

Remarks

Claims 1-3, 5, 7-8, 14, 25-28, 31, 37-39, and 42-48 were pending. No claims were cancelled. Claims 49-51 are added. Therefore, claims 1-3, 5, 7-8, 14, 25-28, 31, 37-39, and 42-51 are pending.

Claim 5 was amended to correct dependency.

Claims 1 and 48 were amended to remove unnecessary claim language.

Support for new claims 49-51 can be found throughout the specification, for example: page 3, line 33 – page 4, line 30; page 26, lines 18-20; page 30, line 16 – page 31, line 15 and page 61, lines 26-30.

No new matter is added by this amendment. No claim amendments were made to distinguish prior art.

Information Disclosure Statement (IDS)

It is noted on page 2 of the Office action that the 1449 form was missing from the file. Enclosed herewith is a copy of the IDS filed on March 27, 2002. As the references are already present in the file, they are not submitted herewith. However, if the Examiner would like a copy of any reference cited in the 1449 form, Applicants will provide a copy.

Specification

The specification has been amended to provide Sequence Identifiers with the description of FIG. 6 on page 7. Therefore, Applicants request that the objection be withdrawn.

35 U.S.C. § 112, second paragraph

Claims 1-3, 5, 7-8, 14, 25, 26, 28, 31, and 42-48 are rejected under 5 U.S.C. § 112, second paragraph as being indefinite. Applicants request reconsideration.

Claim 1 has been amended to remove the language “that decreases FGF-5 expression or activity”, and to clarify that the CTL response is to cells of the neoplasm.

Claim 5 has been amended to depend from non-cancelled claim 1.

In view of these amendments, Applicants request that the 35 U.S.C. § 112, second paragraph rejections be withdrawn.

35 U.S.C. § 112, first paragraph (written description)

Claims 1-3, 5, 7-8, 14, 25, 26, 28, 31, and 42-48 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicants request reconsideration.

As described above, claim 1 has been amended to remove the language “that decreases FGF-5 expression or activity”.

Claim 48 is supported by the present application. Although not expressly stated in the Office action, it appears that the Examiner was concerned with the “therapeutically immunogenic” language in claim 48. In order to expedite prosecution, claim 48 has been amended to remove the unnecessary phrase “that is therapeutically immunogenic”.

In view of these amendments, Applicants request that the 35 U.S.C. § 112, first paragraph rejections be withdrawn.

35 U.S.C. § 112, first paragraph (enablement)

Claims 1-3, 5, 7-8, 14, 25-28, 31, 37-39 and 42-48 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Applicants request reconsideration.


Applicants are currently conducting clinical trials with human patients having FGF-5-positive renal cell carcinomas (RCC), some with metastasis. Currently, there are 10-11 patients enrolled. The trial involves administration of HLA-A3+ or -A2+ FGF-5 epitope peptide sequences, using the methods disclosed in Example 5 (page 30, line 16 – page 17, line 15). At this time, the results of the clinical trial are not yet available, as the average survival time of patients having RCC varies from months to years. However, the Applicants have shown that administration of FGF-5 epitopes does stimulate an immune response. When the clinical trial

data becomes available, Applicants will submit it to the Examiner in the form of a Rule 132 Declaration.

If there are any questions regarding this response, the examiner is invited to telephone the undersigned.

Respectfully submitted,

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